

# Exhibit B



# U.S. Food and Drug Administration

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## CDER Drug and Biologic Approvals for Calendar Year 2006 Updated through July 31, 2006

### New Drug Application (NDA) Approvals:

NDA Number	Proprietary Name	Established Name	Applicant	Chemical Type	Re Class
N021858	Boniva	ibandronate sodium	Hoffmann-La Roche	3	
N021852	Taclonex	calcipotriene; betamethasone dipropionate	LEO Pharma	3	
N021612	Lipofen	fenofibrate	Cipher	3	
N021812	Men's Rogaine	minoxidil	Pharmacia and Upjohn	3	
N021938	Sutent	sunitinib malate	Pfizer	1	
N021247	Aerospan	flutisolid HFA	Forest Labs	3	
N021526	Ranexa	ranolazine	CV Therapeutics	1	
N021868	Exubera	insulin [rDNA Origin]	Pfizer	3	
N021908	Amitiza	lubiprostone	Sucampo	1	
N021313	Clarinet-D 12 Hour	desloratadine; pseudoephedrine sulfate	Schering	5	
N021026	Vusion	miconazole nitrate	Barrier Therapeutics	3	
N021920	naproxen sodium	naproxen sodium	Banner Pharmaceuticals	3	
N021871	Loestrin 24 Fe	norethindrone acetate; ethinyl estradiol; ferrous fumarate	Warner Chilcott	3	

N021632	Eraxis	anidulafungin	Vicuron	1
N021849	Zegerid	omeprazole; sodium bicarbonate	Santarus	4
N021336	Emsam	selegiline hydrochloride	Somerset Pharms	3
N021676	YAZ	drospirenone; ethinyl estradiol	Berlex	2
N021892	OsmoPrep	sodium phosphate monobasic monohydrate; sodium phosphate dibasic anhydrous	Salix	3
N021850	Zegerid with Magnesium Hydroxide	magnesium hydroxide; omeprazole; sodium bicarbonate	Santarus	3,4
N021980	Fluorescite	fluorescein	Alcon Research	5
N021483	Geodon	ziprasidone hydrochloride	Pfizer	3
N022010	Septocaine	articaine hydrochloride; epinephrine	Deproco	5
N021514	Daytrana	methylphenidate	Noven Pharms	2,3
N021897	Vivitrol	naltrexone	Alkermes	3
N021903	NeoProfen	ibuprofen lysine	Farmacon-LL, LLC	2
N021790	Dacogen	decitabine	MGI Pharma	1
N050808	Solodyn	minocycline hydrochloride	Medicis	3
N021928	Chantix	varenicline	Pfizer	1
N021641	Azilect	rasagiline mesylate	TEVA	1
N021860	Sarafem	fluoxetine hydrochloride	Warner Chilcott	3
N021338	Ionys	fentanyl iontophoretic transdermal system	ALZA	3
N021764	brimonidine tartrate	brimonidine tartrate	Alcon	5
N021840	Seasonique	levonorgestrel/ethinyl estradiol and ethinyl estradiol	Duramed	3
N050805	Oracea	doxycycline	CollaGenex	3
N021426	Omnitrope	somatropin [rDNA origin]	Sandoz	5
N021959	Orapred ODT	prednisolone sodium phosphate	BioMarin	3
N021729	Abilify Discmelt	Aripiprazole	Otsuka	3
N021254	Advair HFA	Fluticasone propionate and salmeterol xinafoate	GlaxoSmithKline	3
N021479	Zelapar	selegiline hydrochloride	Valeant	3

N021610	Opana	oxycodone hydrochloride	Endo	3
N021611	Opana	oxycodone hydrochloride	Endo	3
N021976	Prezista	darunavir	Tibotec	1
N021986	Sprycel	dasatinib	Bristol-Myers Squibb	1
N021717	lidocaine; tetracaine	lidocaine; tetracaine	Zars	4
N021937	Atripla	efavirenz; emtricitabine; tenofovir disoproxil fumarate	Gilead Sciences	4
N021949	budesonide	budesonide	AstraZeneca	5
N021529	Implanon	etonogestrel	Organon USA	3
N021502	Anthelios SX	avobenzone; ecamsule; octocrylene	L'Oreal	1,4
N021929	Symbicort	budesonide; formoterol fumarate dihydrate	AstraZeneca	4
N021958	Lamisil AT	terbinafine	Novartis	8
N021910	Normocarb HF	sodium chloride; magnesium chloride hexahydrate; sodium bicarbonate	Dialysis Solutions	3
N021925	Ductact	pioglitazone hydrochloride; glimepiride	Takeda Global	4
N021946	Xolegel	ketokonazole	Barrier Therapeutics	3
N021872	Keppra	levetiracetam	UCB	3

N021612 Liopofen was tentatively approved on 7/15/2004

N021764 Brimonidine Tartrate was tentatively approved on 2/28/2005

### New Drug Application (NDA) Tentative Approvals

NDA Number	Proprietary Name	Established Name	Applicant	Chemical Type
N021915	ondansetron hydrochloride	ondansetron hydrochloride	Baxter	3

N021915 Ondansetron was tentatively approved on 5/26/2006

### New Drug Application (NDA) Tentative Approvals under the President's Emergency Plan for AIDS Relief (PEPFAR):

NDA	Chemical	Ref
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Number	Proprietary Name	Established Name	Applicant	Type	Class
N021943	efavirenz; lamivudine; zidovudine	efavirenz; lamivudine; zidovudine	Aurobindo	4	
N021939	lamivudine; zidovudine; nevirapine	lamivudine; zidovudine; nevirapine	Aurobindo	4	
N021944	lamivudine; zidovudine; abacavir sulfate	abacavir sulfate; lamivudine; zidovudine	Aurobindo	4	

N021943 lamivudine 150mg/zidovudine 300mg Fixed-Dose Tablets co-packaged with efavirenz 600mg Tablets was tentatively approved on 3/06/2006 under  
N021939 lamivudine 150mg/zidovudine 300mg/nevirapine 200mg Tablets was tentatively approved on 6/30/2006 under PEPFAR.  
N021944 lamivudine 150mg/zidovudine 300mg/Copackaged with abacavir sulfate 300mg Tablets was tentatively approved on 07/26/2006 under PEPFAR.

#### Biologic License Application (BLA) Approvals:

BLA Number	Proprietary Name	Proper Name	Applicant	Review Classification
BL125141	Myozyme	alglucosidase alfa	Genzyme	P, O
BL125156	Lucentis	ranibizumab	Genentech	P
BL125151	Eleprase	idursulfase	Shire Human Genetic Therapies	P, O

#### NDA Chemical Type:

- 1 - New molecular entity
- 2 - New ester, new salt, or other noncovalent derivative
- 3 - New dosage form
- 4 - New combination
- 5 - New formulation or new manufacturer
- 7 - Drug already marketed, but without an approved NDA
- 8 - OTC switch

#### Review Classification:

- P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease
- S - Standard Review - Products that do not qualify for priority review.
- O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).